



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,359	03/16/2001	Taeyoung Yoon	49662 [72021]	7721
21874	7590	05/11/2004	EXAMINER	
EDWARDS & ANGELL, LLP			TRUONG, TAMTHOM NGO	
P.O. BOX 55874			ART UNIT	
BOSTON, MA 02205			PAPER NUMBER	
			1624	

DATE MAILED: 05/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/811,359	Applicant(s) YOON ET AL.	
	Examiner Tamthom N. Truong	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 24-27, 30 and 35 is/are pending in the application.
- 4a) Of the above claim(s) 17-22, 32-34, 39-64 and 67 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3 and 5-16 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 24-27, 30 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1624

NON-FINAL ACTION

Applicant's amendment of 04-20-04 has been fully considered. Although the amended claims have overcome the previous 102(b) rejection based on **Brunner** (US'896), an update search yields the following new ground(s) of rejection.

In view of the new ground(s) of rejection, the finality of the previous office action is withdrawn herein.

Claims 23, 28, 29, 31, 36-38, 62, 66 and 68 have been cancelled. Claims 17-22, 32-34, 39-64, and 67 have been withdrawn as being drawn to the non-elected subject matter. Claims are 1-16, 24-27, 30, and 35 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1, 2, 4, 24-27, 30 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 2 recite the phrase "*optionally substituted*" without reciting substituents following said phrase. In the absence of the specific moieties intended to effectuate modification by "substitution" or attachment to the chemical core claimed, the term "*optionally substituted*" renders the claims in which it appears indefinite in all occurrences wherein applicant fails to articulate by chemical name, structural formula or

Art Unit: 1624

sufficiently distinct functional language, the particular moieties applicant regards as those which will facilitate substitution, requisite to identifying the composition of matter claimed.

2. Claims 4, 24-27, 30 and 35 are rejected as being dependent on claim 1 and carrying over all those limitations that are “*optionally substituted*”.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 24-26, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by **Oka et. al.** (JP 10-130150). On page 26, Oka et. al. disclose several compounds (e.g., compounds # 2.2, 2.3, 2.5, 2.6, 2.7) that read on the compounds of the following claims:

a. Claim 1: the compound wherein:

- i. Ar is a mono-substituted phenyl group;
- ii. R₁ is a halogen;
- iii. R₂ and R₃, each represents an alkyl group;

b. Claims 24-26 are inherently anticipated since they depend on claim 1 for the chemical structure. Based on the structural similarity, the compounds of Oka et. al. would inherently have the same biological activity as recited in claims 24-26.

Art Unit: 1624

- c. Claim 30 is anticipated as being dependent on claim 1 for the chemical structure. Also, the preamble of “*wherein in a standard in vitro Na channel functional assay...*” in claim 30 does not result in a structural change of the compound.
 - d. Claim 35: the pharmaceutical composition comprising a compound of claim 1. Note, even though compounds of Oka et. al. are intermediates, they have been isolated, and thus, can be incorporated in a pharmaceutical composition (e.g., topical cream, ointment, etc.).
4. Claims 1, and 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by **Kleemann et. al.** (US 5,849,758 or EP823,431). On column 18 of US’758, Table IX discloses several compounds (e.g., compounds # 83, 84, 86, 88, 92, 94, 96, 99, 101, 105, 108) that read on the compounds of the following claims:
- a. Claim 1: the compound wherein:
 - iv. Ar is a mono-substituted phenyl group;
 - v. R₁ is a halogen;
 - vi. R₂ represents an alkyl group;
 - vii. R₃ is a hydrogen;
 - b. Claims 24-26 are inherently anticipated since they depend on claim 1 for the chemical structure. Based on the structural similarity, the compounds of Kleemann et. al. would inherently have the same biological activity as recited in claims 24-26.

Art Unit: 1624

- c. Claim 30 is anticipated as being dependent on claim 1 for the chemical structure. Also, the preamble of “*wherein in a standard in vitro Na channel functional assay...*” in claim 30 does not result in a structural change of the compound.

Allowable Subject Matter

5. Claims 3, and 5-16 are allowed. The references of Oka et. al. and Kleemann et. al. do not teach 2-(substituted phenyl)-pyrimidinyl compounds having a phenyl or naphthyl group at the 5th position (corresponding to the instant R₂), or having a substituent corresponding to the instant –NR_xR_y (in formula A), or –OR_x (in the formula of the instant claim 15).

Non-elected Subject Matter

6. This application contains claims 17-22, 32-34, 39-64, and 67 drawn to an invention nonelected with traverse in Paper 12-04-03. A complete reply to this office action must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (~10 am ~ 6:30 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at 571-272-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting SPE of 1624, at 571-272-0661.

Application/Control Number: 09/811,359

Page 6

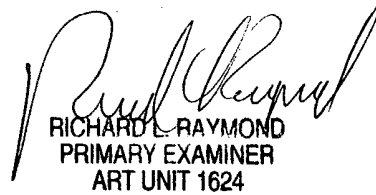
Art Unit: 1624

The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



T. Truong

May 5, 2004



RICHARD L. RAYMOND
PRIMARY EXAMINER
ART UNIT 1624